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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,974

08/27/2003

Joseph Senesac

CRUC:010US/10901498

7068

32425 7590 02/03/2010
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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

02/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/649,974	Applicant(s) SENESAC, JOSEPH	
	Examiner Leon B. Lankford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 20-25,30-32,34,35,40,41,67 and 70-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,26-29,33,36-39,42-66,68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of the species wherein the first chromatographic medium is an anion-exchange medium and wherein the second medium is a dye affinity medium in the reply filed on 9/30/09 is acknowledged.

Claims 1-19, 26-29, 33, 36-39, 42-66, 68 & 69 are considered as they read on the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19, 26-29, 33, 36-39, 42-66, 68 & 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "wherein said...particles...are retained on said first...medium" renders the claims indefinite. As chromatography is a separation technique based on the differing times (elution rates) a particular substance in a mixture elutes from a medium when the mixture is applied to that medium, all (or at least most) substances would be to some degree retained in the medium and as such the phrase in question does not serve to adequately limit and define the claimed invention. It would appear that applicant's invention seeks to require that the particles be retained on the medium until a further step is applied to said particle/medium combination, but the

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claims fail to step forth such a method if that is in fact the subject matter applicant regards as their invention. If that is the subject matter applicant regards as the invention then the essential method step must be claimed.

Further, the language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds". See, e.g., the following decisions: *In re Hammack*, 427 F.2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); *In re Venezia* 530 F.2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); *In re Goffe*, 526 F.2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); *In re Watson*, 517 F.2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); *In re Knowlton* 481 F.2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). In the instant claim 1, applicant should make it clear what "metes and bounds" are required for the particles to be retained on the first medium (step a) and subsequently which conditions are required for the particle to elute (step b).

Applicant's repeating use of "said eluate" in claim 1 renders the claim and its dependents indefinite. As this is a multi-step process which multiple eluates, careful distinction between the eluates is necessary for applicant to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Step (c) of claim 1 requires the addition of an eluate to a second medium and then step (d) collects particles from "said eluate" and this is confusing and would not appear to be what applicant's intentions are. It would appear that applicant should clarify that step (c) produces a different eluate from what is introduced to the medium- the claims currently do not make that clear.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-19, 26-29, 33, 36-39, 42-66, 68 & 69 rejected under 35 U.S.C. 103(a) as being unpatentable over Shabram et al (5837520) in view of Boey et al(5385837).

Claims 1-19, 26-29, 33, 36-39, 42-66, 68 & 69 are considered as they read on the elected species.

Shabram teaches a two step adenovirus purification process wherein a virus preparation is added to a DEAE column, retained on said column, eluted from said column and then the resulting virus preparation which has been eluted is applied to a second type of chromatographic medium to further purify the virus. It is notoriously old and well known in the art of protein or virus or even adenovirus purification to use serial chromatographic techniques which use different (or even redundant) mediums in order to purify the protein or virus- Applicant would not appear to dispute this.

Shabram differs from the claimed invention because Shabram does not teach using dye affinity chromatography for the second step of their process. However at the time the invention was made it would have been obvious to one of ordinary skill in the art to combine any known chromatographic medium in a serial technique to purify adenoviruses because the prior art clearly motivates one to use whatever known purification techniques are in the art to achieve the greatest purity possible. Further, Shabram teaches using two techniques in their second step which are both closely analogous to dye affinity, i.e. metal affinity and hydrophobic interaction.

Specifically, it would have been obvious to use commercially available and notoriously old and well known dye affinity chromatographic medium, particularly sepharasoie blue, or more particularly BioSpera Blue Trisacyl, because they are commercially available medium which are known to be useful for proteinaceous substance separations and are known to be work differently than anion exchange columns and as such would meet the criteria for adenovirus purification used in Shabram (and well known in the art).

More specifically, it would be obvious to use an anion exchange step followed by a dye affinity step because Boyer et al teaches that a DEAE-blue affinity dye protocol has been successfully used to purify other proteinaceous materials (Example 3) from a complex biological mixture.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary because the prior art has previously combined chromatographic techniques in series to purify adenovirus and the specific AE-dye series has been successfully used to purify other proteinaceous materials.

Applicant is directed to pages 12-13 of *KSR v Teleflex* (500 US 398 2007) “ ... the Court has held that a “patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The

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combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” “When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either ***in the same field or a different one(emphasis added)***. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” Clearly in the instant case the substitution of dye affinity medium for the metal affinity or hydrophobic interaction media in the second chromatographic step of Shabram would have been obvious at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon B. Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Fri 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Leon B Lankford
Primary Examiner
Art Unit 1651